REMARKS

As discussed herein, Applicants respectfully request reconsideration and withdrawal of the rejections of record.

Status of the Claims

The Office Action rejects all of the claims (claims 13-20) that were pending. By this Amendment, method claims 19 and 20 are canceled without prejudice or disclaimer. New method claims 21 and 22 are now presented. Thus, claims 13-18, 21, and 22 will be pending upon entry of this Amendment.

Response to Written Description Rejection

Claims 19 and 20 are rejected under 35 USC § 112, ¶ 1, as allegedly lacking adequate written description. The rejection states that the specification does not contain a full description of the inventive compounds as 5-HT_4 agonists and antagonists, and that the claimed method reaches out to diseases not described in the specification. Applicants respectfully disagree with the rejection as understood.

In order to expedite prosecution, claims 19 and 20 have been canceled without prejudice or disclaimer. New claims 21 and 22 recite the compounds and the disease GERD against which the compounds are employed. Thus, the rejection is believed to be moot. Moreover, the specification specifically describes utility of the compounds against GERD. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Response to Enablement Rejection

Claims 19 and 20[1] are rejected under 35 USC § 112, ¶ 1, as allegedly lacking enablement. The rejection states that biological pathways by themselves are devoid of utility unless inexorably linked to treatment of disease, and that a nexus between 5-HT_4 activation or inhibition and the recited diseases is not established. Applicants respectfully disagree with the rejection as understood.

In order to expedite prosecution, claims 19 and 20 have been canceled without prejudice or disclaimer. New claims 21 and 22 recite the compounds and the disease GERD. Thus, the rejection is believed to be moot. Moreover, the specification enables the skilled artisan to utilize the claimed compounds without undue experimentation against

[1] The rejection actually states that claims "10-20" are rejected. Applicants presume that claims 19-20 were intended and have responded accordingly. If this is incorrect, clarification is respectfully requested.

GERD by disclosing subject compounds, their preparation, use, dosages, and supporting biological data. *See, e.g.*, pp. 30-32. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Response to Obviousness Rejection

Claims 13-20 are rejected under 35 USC § 103(a), as allegedly being obvious over US Patent No. 6,624,162 to Uchida et al. ("UCHIDA"). The rejection states that UCHIDA has an effective filing date of 2 October 2001 and is prior art under § 102(e). The rejection further states that UCHIDA claim 6 has a butyl in the R^3 position, whereas Applicants' claim 17 has an isobutyl; and that UCHIDA discloses that butyl and isobutyl are optional choices in UCHIDA. The rejection concludes that the skilled artisan would have been motivated to replace butyl with isobutyl to attain the claimed invention.

Applicants respectfully submit 35 USC § 103(c)(1) dictates that UCHIDA is not available for a § 103(a) rejection of the present claims. More specifically, the rejection relies on § 102(e) as the prior art provision; the UCHIDA inventive entity is different from the present inventive entity; and Applicants hereby declare, in accordance with MPEP § 706.02(l)(2):

> UCHIDA and the presently claimed invention were, at the time of the invention, owned by the same person or subject to an obligation of assignment to the same person.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Response to Double-Patenting Rejection

Claims 13-20 are rejected for alleged obviousness-type double patenting over claims 1-11 of UCHIDA and provisionally rejected on the same grounds over the claims of Appln. No. 10/617,920 ("UCHIDA II"). The rejection states that the present claims are not identical to the UCHIDA claims, but that the claims are not patentably distinct, for the same reasons set forth in the obviousness rejection, above.

Applicants respectfully traverse the rejection. A double patenting analysis refers to the invention recited in the *claims* of the applied patent, not the entire specification. In re Kaplan, 789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986); *see also* Geneva Pharm. v. Glaxosmithkline PLC, 349 F.3d 1373, 68 USPQ2d 1865 (Fed. Cir. 2003). Otherwise, a rejection would amount to a back-door prior art rejection without establishing whether an applied patent actually is prior art. *Id.* The present rejection's use of the entire specification in support of the double-patenting rejection amounts to an improper application of UCHIDA

as prior art to the pending claims. For example, the rejection relies on the assertion that UCHIDA "expressly taught that any species within the disclosed genus, especially the preferred genus, would be an effective 5HT4 ligand." For this reason alone, reconsideration and withdrawal of the rejection are respectfully requested.

Taking the UCHIDA claims as the subject matter to be applied to the present claims, it is apparent that the UCHIDA claims do not disclose or suggest the presently claimed invention. UCHIDA claim 1 recites a genus wherein R^6 is H, C_{1-6} alkyl, or C_{1-6} alkoxy(C_{1-6})alkyl. In contrast, the present claims recite an R^3 defined as (a) 3 to 6 carbon branched alkyl or (b) 3 to 6 carbon straight or branched alkyl which is substituted by 1 to 6 carbon alkoxy; with the proviso that when said alkoxy substitutes a terminal carbon, then said alkyl (b) is branched alkyl. Claim 17 more specifically recites certain R^3 groups, such as dimethyl butyl, that are not disclosed or suggested by the UCHIDA claims. Absent evidence to the contrary, a claimed genus does not disclose or suggest an included subgenus or species. The rejection does not cite recitations in the UCHIDA claims that alone allegedly render the present claims obvious. A rejection based on the claims being encompassed by the UCHIDA claims and in view of the specification is believed to be improper. Kaplan, *supra*.

Finally, biological data of record are believed to demonstrate unexpected properties in the claimed compounds. At pp. 29-30 of the specification, data show significantly improved attributes of claimed compounds over comparator compounds. The data show that comparator compounds A and B exhibit significantly lower dofetilide / $5HT_4$ binding Ki ratios than the inventive examples shown in the table. The rejection does not appear to consider the data of record.

The foregoing arguments are believed to apply to as well to UCHIDA II. Also as to UCHIDA II, Applicants respectfully request that, if the rejection is to be maintained despite the above remarks, it be held in abeyance at least until UCHIDA II has allowed claims that the examiner believes conflict with the present claims.

Thus, Applicants respectfully submit that all of the present claims are patentably distinct from the cited claims of UCHIDA.

Conclusion

In view of the above, Applicants respectfully submit that all of the pending claims are allowable in their present form, and that the application is otherwise in condition for allowance. The Examiner is respectfully requested to withdraw the rejection and, as the next official action, to provide a Notice of Allowance.

If any issues remain which can be resolved by a telephone conference, or should the Examiner have any questions or comments regarding this matter, the Examiner is respectfully invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,

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